By the present "Reply to Office Action dated October 23, 2001," claims 52 and 56 have been deleted and have been replaced by new claims 67 and 68 respectively. Therefore, Applicant submits that the objection to claims 52 and 56 is rendered moot. Claims 65 and 66 have been amended accordingly and as such, Applicant requests that this objection be withdrawn. Applicant has also submitted amended drawings with proposed changed shown in red. It is requested that these drawings be approved to that corrected drawings can be filed. Reconsideration is respectfully requested in light of the amendments being made hereby and of the following remarks.

Claims 22-33, 35-39, 41-49 and 52-66 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 5,240,711 (Hille et al.), U.S. 4,390,520 (Nagai et al.) or U.S. 5,225,199 (Hidaka et al.) each by itself or in combination.

Rejection of Claims 22-33, 35-39, 41-49 and 52-66 under 35 U.S.C. 103(a)

Claims 22-33, 35-39, 41-49 and 52-66 have been rejected as being unpatentable over U.S. 5,240,711 (Hille et al.), U.S. 4,390,520 (Nagai et al.) or U.S. 5,225,199 (Hidaka et al.) each by itself or in combination. It is respectfully submitted that claims 22-33, 35-39, 41-49 and 53-6 in their present form are patentably distinct from the prior art.

According to the Office Action, the claims pending in the application stand rejected under 35 U.S.C. 103(a) as being unpatentable over any of Hille '711, Nagai '520 and Hidaka '199. All of the claims contain the following limitation from claim 22: "...a backing layer comprising a unidirectional elastic material having an elasticity of at least 20%." As explained below, none of the references teach or suggest this limitation.

Referring to Hille '711, the reference discloses a transdermal therapeutic system for the controlled release of buprenorphine, which is the active component. The specific backing layer of Hille '711 is disclosed at col. 3, lines 9-14, where it states "The backing layer which is impermeable to the active substance may consist of a flexible or inflexible material." The reference continues to state that substances suitable for the production of the backing layer are polymeric foils and metal foils, such as aluminum foil which may be used alone or coated with a polymeric substrate.

Applicant submits that the aforementioned disclosure of a backing layer by Hille '771 has the ability to be flexed or bent. Applicant respectfully submits that Hille '711does not teach, nor suggest, the use of a backing layer having a longitudinal elasticity, such as according to the present invention. Examiner contends in point 5 that the flexible backing layer is the same as an elastic backing layer. A flexible backing layer, as is disclosed by Hille '771, cannot be equated with an elastic backing layer, such as is in the present invention because the term "flexible" characterizes the property of being flexed, bent, or folded without breaking. However, the term "elastic" characterizes the property of being easily stretched or expanded and resuming its former shape. These two terms refer to two different characteristics and so something that is elastic is not necessarily flexible and vice versa. Therefore, Applicant respectfully submits that the disclosure by Hille '771 of a flexible backing layer does not disclose a backing layer comprising a unidirectional elastic material having an elasticity of at least 20%. Hidaka '199 discloses a pharmaceutical plaster comprising a film layer, which is composed of a film layer having a thickness of 0.5 to 4.9 μm, a strength of 85 g/mm and elongations of

30% to 150% in the two directions intersecting substantially at a right angle and an elongation ratio of 1.0 to 5.0, as stated at col. 2, line 67 – col. 3, line 6. An additional backing sheet is laminated through an adhesive layer with a higher adhesive force than 3 g/12 mm, partially or wholly on the other-side surface of said film layer..." (Col. 3, lines 11-14 and col. 3, lines 30-33).

Applicant points out that Examiner, in point 5, states that the film layer of Hidaka '199 represents the backing layer. It is Applicant's opinion that the Examiner is mistaken regarding this point and that the film layer and the backing layer are two singular, individual and distinct layers from each other. Applicant respectfully refers Examiner to Figs. 1 and 3 of Hidaka '199 and to the brief description of the drawings (col. 3). The film layer is represented by numeral 3 in Fig. 1, numeral 1 in Fig. 2 and numeral 1 in Fig. 3. Alternatively, the backing layer is represented by numeral 1 in Fig. 1, is not shown in Fig. 2 and numeral 3 in Fig. 3. The backing layer is further disclosed at col. 7, line 60 – col. 8, line 30. However, Applicant submits that there is no disclosure of the backing layer of Hidaka '199 being a unidirectional elastic material having an elasticity of at least 20%. Nagai '520 is directed to an antiphlogistic analgesic adhesive, of which the backing layer is disclosed at col. 2, line 68 – col. 3, line 6. The substrate of Nagai '520 has the property of expanding in at least one direction to prevent a disagreeable sense of tension. Applicant respectfully submits that although the backing layer of Nagai '520 may be flexible and elastic, the wording "...expanding in at least one direction" is not a clear and unambiguous description of a unidirectional elastic material having an elasticity of at least 20% and as such, one skilled in the art would not be able to derive the present

invention from the disclosure of Nagai '520, even in combination with the other cited prior art.

To establish a 35 U.S.C 103(a) *prima facie* case of obviousness, there must be some motivation or suggestion in the references to combine the reference teachings. Hille '711, Hidaka et al. '199 and Nagai et al. '520, separately or in combination, neither teach nor suggest such combination, but each rather suggests a system that addresses a problem different from what the present invention addresses. For example, Hille '711 is directed to providing buprenorphine transdermally over a period of at least 24 hours. This is addressed via a specific reservoir composition and a flexible backing layer. There is no hint or suggestion of a backing layer having an elastic characteristic.

Nagai '520 addresses adhering the system firmly to the skin for a desired period of time without leaving a residue on the skin (col. 2, lines 4-6). The solution to this is to provide a flexible and/or elastic backing layer, but there is no suggestion of a backing layer having the specific unidirectional elasticity as provided in the present invention, nor does it address the problem of curling effect as does the present invention.

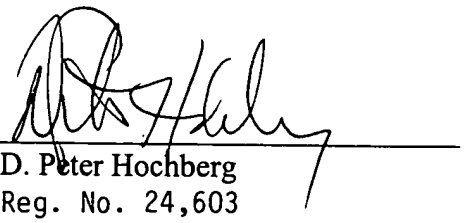
Hidaka '199 is directed to the problem of enabling the transdermal absorption of a drug with reduced skin rash and without breakage or peeling of the system. The solution is a system having a polyester film layer having a specific thickness, strength and an elongation of between 30% and 150% in a two directional manner intersecting at right angles, rather than unidirectionally as in the present invention.

Conversely, the present invention seeks to provide a system which is pleasant for the user during long-term use (i.e. more than 24 hours). The present invention also seeks

to address the problem of curling effect during the manufacture of the system, which is not addressed by any of the prior art references. The solution to this problem is to create a system having a backing layer comprising a unidirectional elastic material having an elasticity of at least 20%. Applicant submits that a person having ordinary skill in the art seeking to create a system having improved long-term wearing ability for the user would select a material having a flexibility and elasticity as large as possible. It was during production of a system having a flexibility and elasticity as large as possible that the problem of curling effect ensued. Applicant submits that the system best suited to provide highest user comfort as well as the least amount of curling effect during production is one having a backing layer with an elasticity of at least 20%. It would not be obvious for a person skilled in the art to reach this conclusion by merely combing the aforementioned prior art references. It is therefore respectfully requested that the application defined in the claims is patentably distinguishable over the art under 35 U.S.C. 103(a).

For the foregoing reasons, it is respectfully submitted that the present application is in condition for allowance, and such action is earnestly solicited. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

By: 

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Enc. – Marked Up Claims; Clean and Marked-Up Substitute Specifications; Proposed amended drawings
DPH/sm

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Date: January 23, 2002 Sean Mellino
Sean F. Mellino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Thomas Hille and Lothar Deuer
Serial No.	:	09/486,266/Conf. No. 3529
Filing Date	:	May 3, 2000
Examiner	:	I. Ghali
Group Art Unit	:	1615
Title	:	Transdermal Therapeutic System Comprising a Reservoir Type Pressure Sensitive Adhesive Layer and a Back Layer with Uni-directional Resilience
Attorney File	:	RO0254US (#90568)

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Commissioner for Patents
Washington D.C., 20231

MARKED UP CLAIMS

65. (Amended) The transdermal therapeutic system of claim [34] 58 wherein the fabric or film comprises pores having a size [of at least] less than or equal to 400 μm^2 embracing an areal proportion of between 10% and 50% of said fabric or film.

66. (Amended) The transdermal therapeutic system of claim [34] 58 wherein the fabric has a number of warp threads in the range of 300 to 350 per 10 cm of unextended fabric and a number of weft threads in the range from 100 to 140 per 10 cm of unextended fabric.

* * *